K121286 p. 1/10

SEP 28 2012

Special 510(k) Summary
for *EPIC™ 10* by Biolase Technology, Inc.
(As required by 21CFR 807.92)

1. GENERAL INFORMATION

Date Prepared:	April 20, 2012
Company:	Biolase Technology, Inc. 4 Cromwell Irvine, CA 92618 Tel: (949) 361-1200 Fax: (949) 273-6687
Submitter:	Robert Y. Yang Global Regulatory Affairs Manager Tel: (949) 226-8147 e-mail: ryang@biolase.net
Contact:	Ehab Esmail VP, Regulatory, Quality and Clinical Tel: (949) 226-8469 e-mail: eesmail@biolase.net

2. NAMES / REGULATIONS

Trade/Device Name:	***EPIC™ 10***
Common Name:	Diode Laser
Regulation Number:	21CFR 878.4810, and 21CFR 890.5500
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology; and infrared lamp
Regulatory Class:	II
Product Code:	GEX, ILY

3. PREDICATE DEVICES

- ***ezlase™*** by Biolase Technology, Inc. K083069, K083595, K061898, and K082938
- ***iLase™*** by Biolase Technology, Inc. K093852

K121286 p. 2/10

4. DEVICE DESCRIPTION

The ***EPIC™ 10*** system uses an Indium Gallium Arsenide Phosphorous (InGaAsP) solid state laser diode to emit infrared laser energy which is transmitted via a flexible fiber optic cable to a hand piece that emits the energy to the target site. A visible light is emitted at the same time to visually identify the treatment location. The ***EPIC™ 10*** Laser System is comprised of a Base Console, a detachable delivery system, tips, and a wireless footswitch. Various types of the single use tips are included for different applications and the device is activated by means of a wireless footswitch. The ***EPIC™ 10*** Laser is a surgical and therapeutic device designed for a wide variety of oral soft tissue procedures and dental whitening, as well as for use in providing temporary relief of minor pain.

5. INDICATIONS FOR USE

The indications are identical to that of the previously cleared predicate systems.

1. Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
- Vestibuloplasty
- Tissue retraction for impression

K121286 p. 3/10

2. Laser Periodontal Procedures

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

3. Whitening

- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth

4. Pain Relief

- Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

6. DEVICE TECHNOLOGICAL CHARACTERISTICS

The device ***EPIC™ 10*** system has the same fundamental technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices. A summary of the technological characteristics of this device in comparison to those of the company's owned predicate devices is included in the body of the special 510(k) submission.

7. PERFORMANCE ASSESSMENT

Non-clinical performance data is not presented. An Evaluation Report including the references, literature and publications is included in the 510(k) submission for the demonstration of safety and effectiveness of this device and to support substantial equivalence to the company's owned legally marketed devices.

The clinical test for the therapeutic heating device indications (Pain Therapy) listed in Item 4 of the IFU have been conducted with human subjects and the performance data demonstrated that the device can perform the pain therapy as described in the indication for use safely and effectively.

K121286 p. 4/10

8. CONTRAINDICATIONS

*The contraindications are identical to that of the previously cleared **ezlase**™ and **iLase**™ system by Biolase Technology, Inc.*

All clinical procedures performed with ***EPIC™ 10*** must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, malignancies, bleeding disorders, sleep apnea, immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

9. SUBSTANTIAL EQUIVALENCE

The purpose of this Special 510(k) is to consolidate the current ***ezlase***™ systems and the ***iLase***™ system (K083069, K083595, K061898, K082938, and K 093852). It is a combination of indications for use and ***EPIC™ 10*** system relies upon the company's owned legally marketed devices and no new indications for use are added. The design changes do not affect or potentially alter the fundamental scientific technology of the device. Based on the information presented in this Special 510(k) the combined system ***EPIC™ 10*** is substantially equivalent to the sum of the legally marketed devices: ***ezlase***™ and ***iLase***™ systems.

The predicate device comparison table of the technological characteristics of the new device in comparison to those of the predicate device and the comparison table of the indications for use for each predicate and the subject device are shown in Appendix 1.

10. CONCLUSION

No new indications are added in this Special 510(k) and the device modifications do not potentially alter the fundamental scientific technology of the device. Substantial Equivalence for the ***EPIC™ 10*** system has also been determined through comparison to the company's previous cleared devices. This Special 510(k) submission demonstrates that the ***EPIC™ 10*** system is as safe, as effective, and performs as well as the predicate devices.

Device Name / Features	ezlase™	ezlase™	ezlase™	ezlase™ 10W	iLase™	EPIC™ 10	
Manufacturer	Biolase Technology, Inc.	Biolase Technology, Inc.	Biolase Technology, Inc.	Biolase Technology, Inc.	Biolase Technology, Inc.	Biolase Technology, Inc.	
K-Number	061898 January 26, 2007	K082938 December 22, 2008	K083595 April 14, 2009	K083069 November 23, 2008	K093852 March 12, 2010	Pending	
Laser Classification	IV(4)	IV(4)	IV(4)	IV(4)	IV(4)	IV(4)	√
Materials	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	√
Dimensions	3.5in x 7.0in x 2.5in (8.5cm x 18cm x 6cm)	3.5in x 7.0in x 2.5in (8.5cm x 18cm x 6cm)	3.5in x 7.0in x 2.5in (8.5cm x 18cm x 6cm)	3.5in x 7.0in x 2.5in (8.5cm x 18cm x 6cm)	4.7in x 4.0in x 2.8in (11.9cm x 10.2cm x 7.1cm)	5.7in x 4.4in x 6.5in (14.5cm x 11.2cm x16.5cm)	√
Weight	2 lbs (1.0kg)	2 lbs (1.0kg)	2 lbs (1.0kg)	2 lbs (1.0kg)	1.69 lbs (0.66kg)	2.5 lbs (1.1kg)	√
Operating Voltage	100 - 240 ~ at 2A	100 - 240 ~ at 2A	100 - 240 ~ at 2A	100 - 240 ~ at 2A	90 - 230 VAC	100 - 230 ~ at 2A	√
Current Frequency	47 - 63 HZ	50 - 60 HZ	50 - 60 HZ	50 - 60 HZ	50 - 60 HZ	50 - 60 HZ	√
Laser Medium	GaAlAs, InGaAsP	InGaAsP	GaAlAs, InGaAsP	InGaAsP	InGaAsP	InGaAsP	√
Wavelength	815 ± 15nm, 935 ± 15nm	940 ± 15nm	810 ± 15nm, 940 ± 15nm	940 ± 15nm	940 ± 15nm	940 ± 10nm	√
Max Output	7 watts	12 watts	10 watts	10 watts	3.0 watts	10 watts	√
Power Modes	Continuous, Pulse Modulation	Continuous, Pulse Modulation	Continuous, Pulse Modulation	Continuous, Pulse Modulation	Continuous, Pulse Modulation	Continuous, Pulse Modulation	√
Pulse Repetition Rate	Up to 10KHz	Up to 10KHz	Up to 10KHz	Up to 10KHz	Up to 10KHz	Up to 20KHz	√
Pulse Duration	0.1 ms - 9.9 sec	0.05 ms - 10 sec	0.05 ms - 10 sec	0.06 ms - 10 sec	0.1 ms / 1 ms	0.01ms - 10 sec	√
Pulse Interval	0.1 ms - 9.9 sec	0.05 ms - 10 sec	0.05 ms - 10 sec	0.06 ms - 10 sec	0.2 ms / 1 ms	0.01ms - 10 sec	√
Aiming Beam	Laser Diode, max 1mW, 630-670nm, class 3B	Laser Diode, max 3mW, 630-670nm, class 3B	Laser Diode, max 3mW, 630-670nm, class 3B	Laser Diode, max 3mW, 630-670nm, class 3B	Laser Diode, max 3mW, 630-670nm, class 3B	Laser Diode, max 1mW, 635 ± 10nm , class 3B	√
Indications for Use	Approved Indication as per K061898	Approved Indication as per K082938	Approved Indication as per K083595	Approved Indication as per K083069	Approved Indication as per K093852 with "Tissue retraction for impression"	Same as those indications cleared for K061898, K082938, K083595,K083069 and K093852	√

K121266 p. 5/13

Predicate	*ezlase™*	*ezlase™*	*ezlase™*	*ezlase™ 10W*	*iLase™*	*EPIC™ 10*
510(k) No.	K061898	K082938	K083595	K083069	K093852	K121286
Indications for Use	**1.Dental Soft Tissue Indications** Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications: • Excisional and incisional biopsies • Exposure of unerupted teeth • Fibroma removal • Frenectomy			**1.Dental Soft Tissue Indications** Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications: • Excisional and incisional biopsies • Exposure of unerupted teeth • Fibroma removal • Frenectomy	**1.Dental Soft Tissue Indications** Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications: • Excisional and incisional biopsies • Exposure of unerupted teeth • Fibroma removal • Frenectomy	**1.Dental Soft Tissue Indications** Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications: • Excisional and incisional biopsies • Exposure of unerupted teeth • Fibroma removal • Frenectomy

	• Frenotomy • Gingival troughing for crown impressions • Gingivectomy • Gingivoplasty • Gingival incision and excision • Hemostasis and coagulation • Implant recovery • Incision and drainage of abscess • Leukoplakia • Operculectomy • Oral papillectomies • Pulpotomy •Pulpotomy as an adjunct to root			• Frenotomy • Gingival troughing for crown impressions • Gingivectomy • Gingivoplasty • Gingival incision and excision • Hemostasis and coagulation • Implant recovery • Incision and drainage of abscess • Leukoplakia • Operculectomy • Oral papillectomies • Pulpotomy •Pulpotomy as an adjunct to root	• Frenotomy • Gingival troughing for crown impressions • Gingivectomy • Gingivoplasty • Gingival incision and excision • Hemostasis and coagulation • Implant recovery • Incision and drainage of abscess • Leukoplakia • Operculectomy • Oral papillectomies • Pulpotomy •Pulpotomy as an adjunct to root	• Frenotomy • Gingival troughing for crown impressions • Gingivectomy • Gingivoplasty • Gingival incision and excision • Hemostasis and coagulation • Implant recovery • Incision and drainage of abscess • Leukoplakia • Operculectomy • Oral papillectomies • Pulpotomy •Pulpotomy as an adjunct to root

	canal therapy • Reduction of gingival hypertrophy • Soft tissue crown lengthening • Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa. • Vestibuloplasty **2.Laser Periodontal Procedures** • Laser soft tissue curettage • Laser removal of diseased, infected, inflamed and necrosed soft tissue within the			canal therapy • Reduction of gingival hypertrophy • Soft tissue crown lengthening • Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa. • Vestibuloplasty **2.Laser Periodontal Procedures** • Laser soft tissue curettage • Laser removal of diseased, infected, inflamed and necrosed soft tissue within the	canal therapy • Reduction of gingival hypertrophy • Soft tissue crown lengthening • Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa. • Vestibuloplasty • Tissue retraction for impression **2.Laser Periodontal Procedures** • Laser soft tissue curettage • Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal	canal therapy • Reduction of gingival hypertrophy • Soft tissue crown lengthening • Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa. • Vestibuloplasty • Tissue retraction for impression **2.Laser Periodontal Procedures** • Laser soft tissue curettage • Laser removal of diseased, infected, inflamed and necrosed soft tissue within the

C/9 9821271

	periodontal pocket • Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)	**3.Whitening** • Light activation for bleaching materials for teeth whitening • Laser-assisted whitening/bleaching of teeth	**4. Pain Therapy** • Topical heating for the purpose of	periodontal pocket • Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)	pocket • Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)	periodontal pocket • Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.) **3.Whitening** • Light activation for bleaching materials for teeth whitening • Laser-assisted whitening/bleaching of teeth **4.Pain Therapy**

			elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle			• Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

4,212,856 7/10/80

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biolase Technologoy, Incorporated
% Mr. Robert Y. Yang
Global Regulatory Affairs Manager
4 Cromwell
Irvine, California 92618

SEP 28 2012

Re: K121286
Trade/Device Name: EPIC™ 10
Regulation Number: 21 CFR 878.4810, 890.5500
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology, Infrared lamp
Regulatory Class: II
Product Code: GEX, ILY
Dated: September 17, 2012
Received: September 20, 2012

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121286 p. 1/2

Indications for Use

510(k) Number (if known): K121286

Device (Trade) Name: *EPIC™ 10*

Indications for Use:

1. Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
- Vestibuloplasty
- Tissue retraction for impression

2. Laser Periodontal Procedures

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

3. Whitening

- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth

Neil R Ogden for m x m
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121286

4. Pain Therapy

- Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R. P. Golden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121286